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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,000	03/16/2004	Thomas Nadackal Thomas		2824

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,000	THOMAS, THOMAS NADACKAL	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7, 17, 20 drawn to a method of preventing, reducing and reversing the toxic side effects of anti-inflammatory drugs comprising administering an effective amount of deprenyl or propargylamine compounds, classified in class 514, subclass 365.

II. Claims 6 and 19, drawn to a composition comprising the compound of claim 1 (deprenyl or propargylamine compounds), classified in class 514, subclass 365.

III. Claims 8, drawn to a method wherein the MAO inhibitor treats, prevents or decreases or reverses the toxic side effects of a gastrointestinal disorder, classified in class 514, subclass 922.

IV. Claims 9, drawn to a method wherein MAO inhibitor prevents or treats gastrointestinal ulcers and provides tissue protection alone **or in combination with other agents**, e.g. proton pump inhibitors, classified in class 514, subclass 925.

V. Claim 10, drawn to a method wherein MAO inhibitor ameliorates the toxic side effects of low dose aspirin and other NSAIDS, classified in class 514, subclass 925.

VI. Claim 11, drawn to a method wherein the MAO inhibitor prevents, decreases or reverses the toxic gastrointestinal effects of NSAIDS consisting of dyspeptic symptoms, gastric and duodenal ulcers, intestinal bleeding, perforation of gastroduodenal mucosa and gastric outlet obstruction, classified in class 514, subclass 925.

VII. Claim 12, drawn to a method wherein the MAO inhibitor prevents, decreases or reverses toxic renal effects of anti-inflammatory drugs and provides cytoprotection alone or with other drugs, classified in class 514, subclass 891.

VIII. Claims 13-16 drawn to a method wherein the MAO inhibitor prevents, decreases or reverses disorders resulting from elevated levels or activities of proinflammatory enzymes consisting of COX-1, COX-2, COX-3, lipooxygenase, phosphodiesterase, angiotensin converting enzyme or leukotriene A4 hydrolase, the disorders selected from, for example, neoplasia and central nervous system disorder, classified in class 514, subclass 365.

IX. Claim 18, drawn to a method wherein the MAO inhibitor preserves and enhances the anti-platelet, cardiovascular or anticancer benefits of aspirin and reduces aspirin resistance when aspirin is administered alone or in combination with other NSAIDS, classified in class 514, subclass 822.

X. Claims 21-21, drawn to a method of treating gastrointestinal ulcers due to causes **other than NSAIDS** comprising administering an effective amount

of a MOA inhibitor alone or in combination with agents used in the treatment of ulcers, classified in class 514, subclass 925.

XI. Claim 24, drawn to a method for treating inflammation, pain or fever comprising administering the composition of claim 6, classified in class 514, subclass 365.

XII. Claim 25, drawn to a method for preventing or treating side effects of COX-2 inhibitors and also provide additional cardiovascular protection comprising administering the composition of claim 6, classified in class 514, subclass 365.

XIII. Claim 26, drawn to a method for accelerating gastrointestinal and other tissue repair comprising administering the composition of claim 6, classified in class 514, subclass 365.

XIV. Claims 27, 32 and 33, drawn to a method of treating arthritis, pain, inflammation, vascular disease and cognitive dysfunction syndrome (dementia) in dogs, cats and other animals comprising administering the composition of claim 6, classified in class 514, subclass 825.

XV. Claim 28, drawn to a method of preventing NSAID toxicity and providing tissue protection by administering the composition of claim 6 when the NSAID is administered along with *other* drugs for the treatment of *a number of conditions*, classified in class 514, subclass 1.

XVI. Claim 29, drawn to a method of providing protection to tissues such as blood vessels, heart and brain comprising administering the composition of claim 6, classified in class 514, subclass 1.

XVII. Claim 30, drawn to a method for preventing or treating diseases caused by increased production, aggregation or deposition of amyloidogenic proteins, e.g. prions comprising administering the composition of claim 6, classified in class 514, subclass 1.

XVIII. Claim 31, drawn to a method of treating an inflammatory disorder (e.g. Alzheimer's disease or cancer) or adverse effects of hormone replacement therapy by reducing the levels of inflammatory mediators comprising administering the composition of claim 6, classified in class 514, subclass 1.

XIX. Claim 34, drawn to a method for preventing and treating anti-inflammatory drug discontinuation disorder comprising administering the composition of claim 6, classified in class 514, subclass 365.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product, deprenyl

can be used in a materially different process of using that product, such as in Parkinson's disease.

Inventions II and I and III-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different effects.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined

process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the Examiner knows from past experience that a telephone election will not be made, see MPEP Sect. 812.01.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 9:00 A.M. - 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

September 17, 2007